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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,959	11/28/2000	Robert O. Dempcy	17682A-003610US	7793

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 07/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/724,959		DEMPCY ET AL.	
	Examiner		Art Unit	
	Bradley L. Sisson		1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 95-103 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 95-103 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Location of Application

1. The location of the subject application has changed. The subject application is now located in Workgroup 1630, Art Unit 1634, and has been docketed to Primary Examiner Bradley L. Sisson.

Specification

2. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states:

All publications and patent applications cited in this specification are herein incorporated by reference as if each individual publication or patent application were specifically and individually indicated to be incorporated by reference.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents.** *See In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA

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1973) (providing that incorporation by reference requires a statement "clearly identifying the subject matter which is incorporated and where it is to be found"); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference "expressly incorporates a particular part" of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6th Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); *cf. Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

4. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

5. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 95, and 97-101 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,485,906.

7. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-13 of U.S. Patent No. 6,485,906 discloses the method for primer extension by incubating a polynucleotide containing a target sequence with one or more oligonucleotide primers complementary to the target sequence, in the presence of a polymerizing enzyme and nucleotide substrate, wherein at least one of the oligonucleotide primers contains a modified base selected from an 3'-substituted pyrazolo[3,4-d]pyrimidine, in place of a purine base.

8. Claims 1-13 of U.S. Patent No. 6,485,906 further discloses the method, wherein at least one of the oligonucleotide primers comprises a covalently attached minor groove binder.

9. Claims 1-13 of U.S. Patent No. 6,485,906 further discloses the method, wherein the incubation is part of a polymerase chain amplification reaction.

10. Claims 1-13 of U.S. Patent No. 6,485,906 further discloses the method for determining the nucleotide sequence of a polynucleotide, the method comprising:

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- a) Incubating the polynucleotide with a modified oligonucleotide array under hybridization conditions; and
- b) Determining to which of the modified oligonucleotides in the array the polynucleotide hybridizes', wherein a plurality of the modified oligonucleotides comprise at least one 3'-substituted pyrazolo[3,4-d]pyrimidine in place of a purine base.

11. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use a method of nucleotide sequencing and amplification in order to achieve the express advantages of a novel probe comprising 3-substituted pyrazolo[3,4-d]pyrimidine in place of a purine base, particularly in the cases in which single- or multiple- nucleotide mismatch discrimination is required.

12. Claims 102 and 103 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,485,906 in view of Beattie (U.S. Patent 5,843,767) (December 1, 1998).

13. Claims 1-13 of U.S. Patent No. 6,485,906 discloses the method of claims 95, and 97-101 as described above.

14. Claims 1-13 of U.S. Patent No. 6,485,906 do not disclose the method wherein the array comprises from 10 to 100,000 different modified oligonucleotides.

15. Beattie teaches the method, wherein the array comprises from 10 to 100,000 different modified oligonucleotides (Column 2, line 44 to Column 3, line 54, Example 7, Column 17, lines 9-28, and Example 11, Column 22, lines 1-18).

16. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein the array

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comprises from 10 to 100,000 different modified oligonucleotides of Beattie into the claims 1-13 of U.S. Patent No. 6,485,906, since Beattie states: "An improved microfabricated apparatus for conducting a multiplicity of individual and simultaneous binding reaction is described." (Abstract) By employing scientific reasoning, an ordinary artisan would have combined and substituted a method, wherein the array comprises from 10 to 100,000 different modified oligonucleotides of Beattie into the claims 1-13 of U.S. Patent No. 6,485,906, in order to improve the analysis of a plurality of target nucleic acid. An ordinary practitioner would have been motivated to combine and substitute a method, wherein the array comprises from 10 to 100,000 different modified oligonucleotides of Beattie into the claims 1-13 of U.S. Patent No. 6,485,906, in order to achieve the express advantages, as noted by Beattie, of an invention which provides an improved microfabricated apparatus for conducting a multiplicity of individual and simultaneous binding reaction.

17. Claim 96 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,485,906 in view of Caskey et al. (U.S. Patent 6,153,379) (November 28, 2000).

18. Claims 1-13 of U.S. Patent No. 6,485,906 disclose the method of claims 95, and 97-101 as described above.

19. Claims 1-13 of U.S. Patent No. 6,485,906 do not disclose the method wherein one of the oligonucleotide primers is extended with a single base. Caskey et al., teach the method wherein one of the oligonucleotide primers are extended with a single base (Column 2, lines 12-15).

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20. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute a method, wherein one of the oligonucleotide primers is extended with a single base of Caskey et al. into the claims 1-13 of U.S. Patent No. 6,485,906, since Caskey et al. state, "The current invention provides both direct information, due to the detection of a specific nucleotide addition, and indirect information, due to the known sequence of the annealed primer to which the specific base addition occurred" (Column 3, lines 22- 26). By employing scientific reasoning, an ordinary artisan would have combined and substituted a method, wherein one of the oligonucleotide primers is extended with a single base of Caskey et al. into the claims 1-13 of U.S. Patent No. 6,485,906, in order to improve the analysis of a plurality of target nucleic acid. An ordinary practitioner would have been motivated to combine and substitute a method, wherein one of the oligonucleotide primers is extended with a single base of Caskey et al. into the claims 1-13 of U.S. Patent No. 6,485,906, in order to achieve the express advantages, as noted by Caskey et al., of a novel invention that provides both direct information, due to the detection of a specific nucleotide addition, and indirect information, due to the known sequence of the annealed primer to which the specific base addition occurred.

Conclusion

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
18 July 2004